# NWX-FDA OC

# Moderator: Irene Aihie

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# 1:00 pm ET

**Coordinator:** Welcome and thank you for standing by. At this time all lines are in a listen only mode until the question and answer portion of today's call. At that time to ask a question you may do so by pressing star and then one on your touch tone phone. Today, all questions will only be taken over the audio.

Today's call is being recorded. If you have any objections you may disconnect at this time. And I will now turn today's call over to Irene Aihie. Ma'am you may begin.

**Irene Aihie:** Thank you. Hello and welcome to today's FDA Webinar. I am Irene Aihie of CDRH's Office of Communication and Education. On June 15, 2016, the U.S. Food and Drug Administration issued a final rule, use of symbols in labeling allowing the use of stand-alone symbols in medical device labeling without adjacent, explanatory text.

The final rule seeks to harmonize the labeling requirements of U.S. and international regulatory bodies with the respect to the use of tools in device labeling.

The FDA also published a new standards recognition notice that modifies the agency's current list of recognized standards, containing standalone symbol to extend the recognition of six standards and to recognize three new consensus standards containing many more standalone symbols.

The focus of today's Webinar is to share information and answer questions about the final rule and the standards recognition notice. Your presenters today will be Tosia Hazlett and Scott Colburn, both from the Office of the Center Director here in CDRH.

Following the presentation we will open the line for your questions related to the topics in this final rule and notice only. Additionally there are other center subject matter experts available to assist with the Q&A portion of our Webinar. Now I give you Tosia.

**Tosia Hazlett:** Thank you Irene. Good afternoon everyone. My name is Tosia Hazlett and I'm a senior policy analyst working specifically on medical device labeling in the Center for Devices and Radiological Health here at the Food and Drug Administration.

For the next 60 to 90 minutes, we'll be covering the following topics - - - the purpose of the Webinar, background, purpose, and scope of the symbol's rule, options for the use of symbols, and the definition of the symbols glossary.

We'll talk about consensus standards, how standards are used. We'll also talk about the Federal Registered Notice Standards Recognition List, number 42 on the use of symbols, the declaration of conformity, and the standard's recognition list.

As stated previously the focus of the Webinar today is to share information and answer questions about the symbols rule and the standard's recognition notice.

For some brief background information on April 19, 2013, the FDA published a proposed rule to revise labeling by explicitly allowing labeling to contain certain stand-alone symbols without adjacent text.

The FDA recognizes a list of standards that contain a number of stand-alone symbols. The FDA received requests to permit the use of stand-alone symbols without adjacent text on domestic device labelling that would make it consistence with symbols used on devices manufactured for European and other foreign markets.

The purpose of this regulatory action is to permit the use of stand-alone symbols in labelling without adjacent, explanatory text if certain requirements are met. And we'll talk about those in a few minutes. It’s also to help harmonize the labeling requirements of the U.S. and international regulatory bodies, to make labeling more user friendly by replacing text that may be small and difficult to read.

And it's expected to reduce costs associated with designing and redesigning labeling for medical devices that are currently marketed in the U.S., the European Union, and other foreign markets.

The scope of the symbols rule includes allowing manufacturers to use symbols without adjacent, explanatory text as allowed by the final rule. But manufacturers also have the option to use symbols with adjacent, explanatory text or no symbols at all.

Included in the scope is a required symbols glossary that may be in paper or electronic format. The final rule explicitly permits the use of stand-alone symbols regardless of the user of the device. That is, whether it's a patient, the caregiver or healthcare professional, if certain requirements are met.

It also allows for the use of the symbol statement Rx only for labeling of prescription devices..

There are basically three options with respect to symbols. You can see that on this slide. No use of symbols, the use of symbols with explanatory text, or the use of stand-alone symbols from a standards development organization's standard, with a symbols glossary.

Now to say a little more about the last bullet, if the stand-alone symbol is included in a standards development organization's standard that is recognized by the FDA, manufacturers may use the symbol in accordance with the FDA recognition.

If the stand-alone symbol is an SDO standard, but the standard is not recognized by FDA, or the symbol is not used according to the specifications for use put out in the FDA recognition, manufactures may themselves determine whether the stand-alone use of the SDO established symbol complies with the Food Drug and Cosmetic Act section 502(c).

This means that the manufacturer determines that the symbol is likely to be read and understood by the customary users of the device. This would be consistence with how industry makes other labeling decisions in terms of compliance with other FDA statutes and regulations.

Under the final rule the FDA retains the authority to determine whether the stand-alone use of a symbol complies with section 502(c) and other requirements of the Food Drug and Cosmetic Act.

While the FDA can take enforcement action against violations as warranted, the FDA does not intend to take enforcement action against the use of a stand-alone symbol unless and until the FDA withdraws its recognition of the standard containing the symbol or publishes a symbol specific Federal Register notice announcing the FDA's determination that the symbol does not comply with section 502(c). Now let's move to the symbols glossary.

A symbols glossary as defined in the rule is a compiled listing of each SDO established symbol used in the labeling for the device, the title and the designation number of the SDO developed standard containing the symbol, the title of the symbol and its' reference number, if any, in the standard. And the meaning or explanatory text of the symbol as provided in the FDA recognition.

Or if the symbol is not in an FDA recognized standard or is not used according to the specifications for use of the symbol set out in the FDA recognized standard, the explanatory text is provided in the standard.

As mentioned previously, the symbols glossary is required but may be in a paper format or electronic format. Additionally the labeling on or within the package containing a device must bear a prominent and conspicuous statement identifying the location of the symbols glossary that is written in English.

Or in the case of articles distributed solely in Puerto Rico or in a territory where the predominant language is one other than English, the predominant language may be used.

In device labeling symbols that did not satisfy these criteria must be accompanied by adjacent, explanatory text. Also the FDA has modified the current list of FDA recognized standards that have standalone symbols.

However before we discuss those changes, Scott will briefly discuss the definition of consensus standards and how they are used.

Scott Colburn: Thank you Tosia. My name again is Scott Colburn. I am the Director of our Standards Program here CDRH. And what I'm going to do today is describe a little bit about the program's authority of using standards and recognizing them through the federal register notice.

Incorporated itself into the federal rule is the allowance on the use of symbols contained in labeling without adjacent text. So first and foremost from the rule, I'm just going to reiterate what was already stated. Symbols established in a standard develop by a standard development organization or SDO may be used in medical device labeling without adjacent explanatory text.

So just taking a step backwards, a consensus standard is a technical document that outlines important criteria about specific topics. In the discussion for today, symbols are what we're discussing that are contained in standards are developed through this process.

But they also are contained in many other processes that are used for a variety of different applications whether it be for premarket or post market and can include certain things like test methods, guidelines, manufacturing specifications, practices, and labeling.

These are developed by stakeholders to include members within regulatory authorities in the FDA. But also with clinicians, manufactures and other experts from academia, et cetera through organizations under the leadership of this standard development organizations and there's a few examples here shown.

Such as AAMI, CLSI, ASQ, ADA, ISO, IEC, ASTM International, etcetera. And there are variety of others that we also collaborate with. These consensus standards used are common to many people, but for the purposes of this Webinar while we are focusing solely on symbols, we have standards that are used with any number of processes.

These include the premarket, post market, compliance, research and other quality system aspects of the industry that we work with. CDRH under its authorities in the Food Drug and Cosmetic Act determines which standards we will recognize for regulatory needs to support its' missionand as such a determined that this process was appropriate for the use of symbols in labeling without adjacent text. Through the rule which I'll be showing in the slide following this, CDRH can also withdraw recognition of all or part of the standard that is either out of date, is no longer published, or may not be appropriate to support the public health and regulatory needs.

And that's where we felt the flexibility of the recognition of standards was appropriate to support the public health need and impacts associated to this rule.

So to just go through the text of what is in 21 USC section 514(c) of the Act, which is our authority for recognition of standards, it states that the agency of publication of federal register or FR can recognize all or part of an international or national standard from the standard development organization.

For which a person may submit a declaration to support a process in which they are using.That may be a premarket process as I mentioned or any other process that is within the Food Drug and Cosmetic Act.

If a person elects to use the standard that is recognized they shall provide a declaration of conformity that certifies that their device is in conformance of such standard and that they may use data or information from that standard to support the requirements under which the Act they're utilizing.

The agency may withdraw such recognition through publication of the federal register if we determine that standard is no longer appropriate for meeting of requirement regarding devices underneath this section of the Act.

And finally the agency will accept a declaration of conformity that demonstrates the device is in conformance with that standard. Unless we find that the data or information submitted to that declaration does not demonstrate that the device is in conformance with the standard.

Or that the standard identified or may be the case, you know, for the topic today that the symbols that are identified are not applicable to the particular device under review.

So with this we recognized standards as mentioned earlier in Tosia's comments and the link to that list recognition is listed on this slide. And list 42 is specific to standards recognized to support the use of symbols in medical device labeling for the final rule.

What it did is update by the currently recognized standards and also recognized three additional standards that are primary databases that cover a variety of the symbols contained in those standards.

To be able to look at those fully we also have the URL listed for where all of our standards that are recognized under the authority. The declaration of conformity can be submitted by a sponsor to certify that a device conforms to applicable requirements of an FDA recognized consensus standard.

The idea behind that is where FDA has recognized a consensus standard. We now feel strongly that use of that standard will help support the actions that are taken and described in the purpose for that declaration.

And as such can reduce the amount of time in supporting data that is needed to support either a premarket application or any part of the actions that are taken in the use standards in the Act.

This slide just exemplifies the standards that were listed in list 42. On the left hand side you'll see both the ISO and the U.S. identical adoptions of the standards 27185, which are the symbols to be used in cardiac rhythm management device labels.

And in the ISO and U.S. adoption of 15223-1 which are the symbols to be used with medical device labels and their general requirements. In addition there's an ASTM standard which has its' focus for symbols and other items for safety in magnetic resonance environment.

And then for new recognitions we have two IEC standards, one which is a database of graphical symbols for use on equipment in IEC 60417. And then also in IEC technical report 60878, graphical symbols for electrical equipment in medical practice.

This standard was a little bit more focused into the industries of medical devices. And then finally the ISO 7000 standard which has its' registration into the ISO database for graphical symbols for use on equipment.

Those standards are the ones that were listed for list 42 and are such applicable to section 514(c) of the Act for the declaration of conformity. And at this time I'd like to turn this back over to (Irene) for any questions.

**Irene Aihie:** We'll now open the line for questions.

Coordinator: If you would like to ask a question please press star and then 1 on your touch tone phone, unmute your phone and record your name as your name is required in order to introduce your question.

So again that's star and then one on your touch tone phone and it will take just a few moments for any questions to queue up. Our first question comes from (Elizabeth). Your line is open.

**(Elizabeth):** Yes. My question is if you do - if you put your symbol in your box and on your IFU, do you still have to create the glossary - the symbol glossary?

**Tosia Hazlett:** Could you repeat your question please?

**(Elizabeth):** If you put all your symbols with the text below in your product - your medical device, do you still have to create the symbol glossary? Is the symbol glossary required?

**Tosia Hazlett:** No. If you have text, and you want to use your adjacent text next to the symbol, that is one of the options that you can choose. And a symbols glossary is not needed. A symbols glossary is needed when you want to use a stand-alone symbol in the labeling.

(Elizabeth): Okay. Thank you so much.

**Coordinator:** Thank you. Our next question from (Cathy) your line is open.

(Cathy): Hi. I have a question regarding if you use the standalone symbol on your primary packaging and then you state that the glossary needs to be in a prominent or conspicuous statement on your packaging, does it need to be on the primary package label or is acceptable to be on the box label?

So say you have a box of 12, does it need to be on each primary package or is it acceptable to be placed on the box label?

**Tosia Hazlett:** In the rule it speaks to the prominent and conspicuous statements that can be located on the package insert. It could also be on the side panel of the package or also electronically.

**(Cathy):** So - but each individual device is labeled. So if you have 12 packages inside the box which are labeled but then you put those 12 inside a box. Is it acceptable to on the outside of the box. Or must each of those 12 items inside be - state where the glossary is?

**Scott Colburn:** Hi (Cathy). This is Scott. I hope to understand your question a little bit better here. But my understanding would be that the labeling or the glossary to support the meaning of the symbols should be contained in an area where the end user of the product would be able to likely understand the meaning of that symbol.

Now in the cases where some products like syringes or needles come in very small packages that glossary would be impossible to put on that product so therefore the rule allows for alternative means such as electronic glossary where someone could go to look up the meaning of that symbol.

Additionally the idea of the glossary is not to become an additional burden within the labeling but you place the information as such that would support your labeling as you would normally have for other parts, say instructions for use or et cetera.

**Woman 3:** So I'm just going - they want to put the glossary on the box. But inside it would be our primary packaging but they do not want to state where the symbol legend is located. Is it acceptable just to be on the outside of the box?

**Terri Garvin:** No, you would need to put where the symbols glossary is located on the outside of your box.

**Woman 3:** Thank you. I needed to hear that to relay that information.

**Coordinator:** Our next question comes from (Lawrence). Your line is open.

**(Lawrence Taub):** (Lawrence Taub). Hello?

**Coordinator:** The line is open.

**(Lawrence Taub):** Yes, hi. We have medical devices that have hazardous chemicals in it. Especially let's say MEK, so we have followed GHS hazard symbols for other products that are not medical devices.

Does - do the listing that you show does that also include the GHS hazard symbols like toxic to aquatic or explosion or flammable? And if it does, do we also need to make changes on our change notice and then submit this to the FDA?

**Terri Garvin:** Hi, this is Terri Garvin I'm with DICE, the Division of Industry and Consumer Education. You're talking about requirements from probably like other agencies such as like the EPA maybe. They maybe include the Materials Data Safety Sheet.

**(Lawrence Taub):** Yes, its Global Harmonized System is what we're trying to build to IOTA. And OSHA is using these for hazard shipments across the country and also overseas.

**Terri Garvin:** Okay, so our role is just specific the information that's required to be in your labeling by FDA.

**(Lawrence Taub):** Okay.

**Terri Garvin:** We can't comment on another agency's label requirements.

**(Lawrence Taub):** Okay, so that's what we needed clarification for because I didn't know if like because the FDA says that we only need to hazard symbols then you guys are trumping what GHS is, or I have to follow and have all my hazard statements and - let's see I'm blanking on the other statements that we need.

But we have to have all the statements listed on the label so.

**Terri Garvin:** When the FDA talks about hazard information, you might be talking about contraindications and risk in that - in that level of information. That's what we're talking about. We're not talking about, again like that information goes on the Materials Safety Data Sheet, if that's…

**(Lawrence Taub):** Okay. Okay. But my - the last question in regards to this is, can we have - like we're required by GHS to have this. Can we have these now on an FDA label or for an FDA product or does that - does that conflict - out of spec?

**Terri Garvin:** So 24 CFR801.15 just talks about what supplier should be on the FDA label. And the thought behind that regulation is that if you have any additional information on your label that makes it difficult to see or understand FDA's required text you may be misbranding your FDA label.

So just as long as there's enough room for the required FDA information you'll be okay. But just keep that in mind.

**(Lawrence Taub):** Okay. Okay. I can tell you right now that there is no room to put on these labels so that's what we're trying to figure out. The amount of text that this regulation on the shipping side is requiring is extraordinary.

So I guess, I don't know if it requires a follow-up call with you to like go through it or, you know, we'll just see and do and just do our symbols and see what happens. I don't - like I just don't want to like step on your toes, but step on their toes.

**Terri Garvin:** That's fine. Just e-mail us at DICE, D-I-C-E, dice@fda.hhs.gov.

**(Lawrence Taub):** Hold on. D-I-C-E at…

**(Terri Garvin):** FDA…

**(Lawrence Taub):** Yes.

**(Terri Garvin):** …H-H-S, harry, harry, spam, .gov.

**(Lawrence Taub):** Okay. All right. I'll give you a - I'll give you a sample of the label and then I guess I'll - who should I speak - who should I attention?

**Terri Garvin:** You can put my name, Terri Garvin.

**(Lawrence Taub):** Okay, Terri…

**Terri Garvin:** Garvin.

**(Lawrence Taub):** G-A-R…

**Terri Garvin:** V-I-N.

**(Lawrence Taub):** V-I-N. All right thank you very much.

**Coordinator:** Our next question comes from (Gladys) your line is open.

**(Gladys):** Yes hi. My question actually relates to the previous questions that he mentioned the GHS. We're in the dental industry and we are required, besides the FDA compliance - FDA's symbol of requirements and also the GHS symbol requirement.

And our packaging is very small, like a four ounce or eight ounce packaging. And GHS as he mentioned there is a lot of information for just hazardous alone and we are struggling, you know, what symbols go on the labels first, or priority symbols.

And again it is hazardous, so for example we have flammable liquids. So we have to have flammable liquid symbol, other hazard symbol that is required by the GHS. So like I suppose going back to his question is, which regulation do we show on our labels that comply for both FDA…?

**Terri Garvin:** Again you can send the question to DICE, dice@fda.hss.gov.

**(Gladys):** Okay. Okay. And the second question with the symbol glossary, I'm not familiar with that. Is that something that is - is that something we can add onto our IFU?

**Terri Garvin:** The glossary allows you to use the stand-alone symbols. That's the underpinning of the rule, so in order to use the symbols you have to have the glossary explaining the text - explaining the symbols.

**(Gladys):** Okay. And is there a sample of how that is shown? A sample label showing the symbol glossary?

**Terri Garvin:** No, but the rule has the requirements listed as to what that glossary has to contain. So if you - if you want…

**Tosia Hazlett:** I can take it. - The symbols glossary has to include a compiled listing of each standards development organization's established standard - that's used in the labeling, the title of the symbol, and it's reference number, if any in the standardand the meaning or explanatory text for the symbol as provided in the FDA's recognition. So that's if you choose the option of using standalone symbols.

**(Gladys):** Oh I see. Okay. Okay. All right and then the - to find more information on the symbol glossary or the standalone is it - the slides, is that available after the presentation?

**Terri Garvin:** You can also again just write to DICE, dice@fda.hss.gov.

**(Gladys):** Okay. Okay. All right I think that's about it as far as my question. Thank you.

**Coordinator:** Our next question comes from (Amy). Your line is open.

**(Amy):** Hi, this may be a stupid question, but in 15223 there's a symbol that points to seeing the instructions for use. So if our glossary was housed in our instructions for use can we simply use that symbol or do we need to write it out?

**Tosia Hazlett:** No it can be used - that symbol can be used since you already have it in the glossary. And it is a standard - it is a symbol that is recognized. A standard recognized by FDA. Further clarification: there has to be a prominent and conspicuous statement on or within the packaging saying where the symbols glossary is located.

**(Amy):** It's in 15-2223 which is the one of the…

**Tosia Hazlett:**

**(Amy):** … standards that you've identified already.

**Tosia Hazlett:** .

**(Amy):** And if I can ask a quick follow-up I think it was to the question that (Kathy) had asked earlier. I'm not sure I understood the answer to it. My understanding is that if we have a sales unit, like a carton that contains several units within it, we are only required to reference that glossary on that sales carton and not the individual units inside?

Or does that have to be on every level of packaging?

**Tosia Hazlett:**

**(Amy):** Or just the glossary?

**Tosia Hazlett:** Yes, the rule states that it has to be in the labeling on or within a package and that it must bear a prominent and conspicuous statement that identifies the location of that glossary.

**(Amy):** So that sounds like it's a little flexible if you were to run out of real estate on an inner, individual piece that's within a sales carton or something like that, so that as long as you had it on the carton, you're…

**Terri Garvin:** No, each device - each device has to carry the label. And so as a part of labeling your devices, each device in your carton has to have its own independent labeling.

So you would need to - if you're going to do it through reference to a Webpage, include on that label where you can find the glossary. You couldn't just do it one time for the carton. It's each device has to be labeled.

**(Amy):** Okay, so in the case of the symbol that states see instructions for use or caution, see instructions for use. There's two different ones. One is a little book that says - it's called the I Book, the other is the caution symbol that says, see instructions for use.

Can they be used without additional language? Or is that something we would have to ask specifically about through the DICE email?

Scott Colburn: So that's, the symbol - the caution symbol, I believe is also a registered symbol on the ISO 7000 standard database and would fall under that. Just to help clarify some of the questions though.

I want to make sure and I'll say this is even to just my understanding, but what we're referring to when we're discussing individual packages and labeling and then the use of symbols, what we're seeing is the idea of the rule behind this was to make it a little bit easier for the small real estate that already has the symbols contained on thembut have the adjacent text to it, you no longer need to have that. And then reference within somewhere appropriate, depending on the

size of the package, where that information for those individual symbols that fall under recognized standard are.

And so this shouldn't - you know, what we're looking for is to be able to simplify your labeling because you don't need to have all the adjacent text for the symbols that are currently already - that are currently on there.

**Tosia Hazlett:** And I think what Scott was also saying earlier too is that it's important for the end user to be able to reference the information in the symbols glossary if there is a question about the meaning of that particular symbol.

**Coordinator:** Thank you, our next question comes from (Chris). Your line is open.

**(Chris):** Yes, hi. I think we're just looking for a little clarification on what is included in the glossary. On one of the slides, it referenced the standard reference numbers for the symbols. Is that something that needs to be included in the glossary?

**Scott Colburn:** Yes.

**Tosia Hazlett:** Yes.

**Scott Colburn:** Yes. Each of the standard or symbols that are contained in the standard have some sort of reference number to them. It may just be, explicitly with the ISO and IEC standards, otherwise just, you know, just giving the title of that if there isn't a specific number or registration number, for example, then that should always be included in the glossary.

**(Chris):** Okay, thank you for clarifying that.

**Coordinator:** Our next question comes from (Alicia). Your line is open.

**(Alicia):** Hi, this is (Alicia). So the question that I have is, we use sometimes, you know, labeling, some symbols for the retail business, for marketing purposes, and so these are not in any of DOs. Is it okay to have these symbols with the description in a glossary?

**Terri Garvin:** If the information is not required by FDA - if I understand you correctly - we really don't have any comment on those symbols. The only thing that I just caution you about is just make sure that the required information by FDA is legible and is understandable, you know, by the user.

**(Alicia):** Okay. All right, thank you.

**Coordinator:** Our next question comes from (Terri). Your line is open. (Terri) your line is open.

**(Terri):** Hello?

**Coordinator:** Yes, your line is open.

**(Terri):** Hi. Just wondering if this symbol usage also applies to software. It sounds like most people are asking about packaging and physical labeling and what not. Does this also apply to icons being used and symbols being used in software?

**Scott Colburn:** Are you referring to the software as a medical device?

**(Terri):** There is - there is software on the medical device that controls the medical device.

**Scott Colburn:** Yes, if it's part of the medical device itself then symbols that would be referring to the, you know, appropriate instructions or, you know, or identifications of such, if they're registered symbols that fall underneath the suite of standards that were recognized, or that are currently recognized, then yes, it would be appropriate.

**(Terri):** Okay. And the glossary can still - does the glossary need to be in the software itself or can it be in a packaging?

**Tosia Hazlett:** It would have to be where it would be conspicuous and prominent so that the user would be able to reference it. So if it's in the software as long as it was accessible or easily referenced.

**(Terri):** Okay.

**Coordinator:** Our next question comes from (Ed). Your line is open.

**(Ed):** Thank you. My question has to also do with nonstandard symbols. I can't see your slides because there's some JAVA issues, but I was wondering if ISO 15223-2 development and validation of these symbols is recognized by the FDA?

And second, a related question is if it is or isn't, do manufacturers - what's the regulation here about if a manufacturer develops a new symbol that's not standardized, but has validation data that show it works without text, how should that be handled?

**Tosia Hazlett:** Could you just restate your question again just so we're clear in responding?

**(Ed):** These are symbols that do relate to risk, but they're not - you can't find a standard symbol that represents a blood drop, let's say for example, on a glucose meter. I'm not aware of any standards that have those right now. So manufacturers will develop their own symbols.

They'll do usability testing, and they'll validate that they're understood without a text label. So my question is, is this still an acceptable practice because you - they would develop a symbol along the lines of ISO 15223-2, which is the part of the ISO standard that's about development of new symbols and how you validate them.

**Irene Aihie:** Hi..

**(Ed):** The other - go ahead.

**Irene Aihie:** While they find that answer for you, this is Irene Aihie here. I just want to let you know, I heard that you are having JAVA issues. If you go to fda.gov/training/cdrhlearn, you can find the slides there - PDF copies of slides.

**(Ed):** Thank you.

**Irene Aihie:** They'll be located under the heading called, Specialty Technical Topics and a subheading called Labeling. You'll see a symbol there that says, brand new, it's highlighted in yellow.

**(Ed):** Thank you.

**Irene Aihie:** You're very welcome.

**(Ed):** So, I guess my first question is if 15223-2, for development and validation of symbols recognized by the FDA?

**Scott Colburn:** That standard has a process standard - how to validate a symbol is not itself recognized because it doesn't contain any actual symbols and then so it didn't pertain to this rule. We know that standard is utilized by several standard developing writing groups with ISO and other organizations.

By itself is not a recognized standard. So if you were to have a consortium symbol, or a symbol that was developed by a particular organization but it's not included in any of the standards,it's not a registered symbol, to speak, or is not a symbol that is contained in a standard, a consensus standard, as defined, then it would not be applicable.

So just to restate that the rule is not specific only to symbols contained in recognized consensus standards, but also in other consensus standards that are identified.

If you do find symbols that may be contained in standards that are not in the current recognition database, then you can forward that to the Center, and we would consider those standards for recognition.

(Ed): What about the situation where it's not a consortium development standard? It's an individual one, developed by a manufacturer who, again, validates it through some validation usability test? But it works without a company text label. Is that something that's permissible?

**Scott Colburn:** Yes, just hold on one moment please.

**Tosia Hazlett:** And hopefully we're answering your question here, but if not, I would say a follow up email would be good.

But the option of accompanying - including explanatory text adjacent to the symbol is what would be needed. And then, as Scott said, , you can always submit a standard for recognition as well.

(Ed): Submit a symbol to the FDA for recognition that isn't an SDO?

**Tosia Hazlett:** No, no, no. Sorry. A standard.

**Scott Colburn:** The symbol itself would have to be contained within a standard the FDA could recognize for it to fall underneath the authority of this rule. So to your point, you utilized a symbol for your - say for a particular company, and you validate it for usability or reasonable understanding.

Because that is not yet in a consensus standard, it's not one that we would be able to recognize, and therefore, it would not be appropriate for that part of the rule. And to understand it here, would need to have an adjacent text to follow.

But I would request that you just submit that question in for me. We'll take another look at - a closer look at that and if, you know, if there's a different interpretation, we'll make sure to have that listed.

**(Ed):** Yes, I guess the question though is can you have a device with a homegrown symbol that you validate, get approved with this new rule, because you follow the validation of the user interface, including a symbol without text that is understandable, readable and actionable?

**Tosia Hazlett:** Would you be referring to one that would be sort of a proprietary symbol?

**(Ed):** Well it could be proprietary. It doesn't have to be. A company might say, we developed this symbol because we couldn't find a suitable one in the standards and we put this out here.

And we're not going to necessary claim ownership of it. A company could do that. But I didn't want to narrow it to proprietary. I wanted to narrow this to symbols that aren't in any recognized standard but have validation data to support their use.

**Tosia Hazlett:** So it wouldn't be one that there's not exclusive rights to for the owner, and it would also be freely available to the public? In those situations -
(Ed): No, that could be the case. Right?

**Tosia Hazlett:** Then the agency believes it would be outside of the SDO standards development process that's called for in the final rule. But a proprietary symbol or one as you described is allowed is accompanied by explanatory text, that would be adjacent to the symbol.

**(Ed):** But if no accompanied text then you're saying - but even there, you could so offer your argument that it works and when you submit your device for a 510K, you have all this evidence to say we have a symbol and it doesn't have accompanied text, but it works in this context.

And we couldn't find a standard symbol that worked in the same context. You may, in fact, compare it to standard symbols verses this homegrown symbol. We found that the homegrown symbol was, in fact, better and it's, you know, at this point and time, not a standard symbol.

But it works throughout a text label because the text label, again, could have all the problems. There's not room, if it's a small display, a handheld device. You know, there could be lots of issues with why you can't have that new homegrown symbol have an accompanying text label.

But in certain interpretations, what I just heard you say was, if you do if you have a homegrown symbol, you should try to use it with a text label?

**Tosia Hazlett:** Yes and this is specifically the rule refers to that in the section on proprietary symbols. If it's accompanied by explanatory text adjacent to the symbol.

**(Ed):** And that's always when the symbol is presented on a faceplate or on a small display, not just in the glossary?

**Tosia Hazlett:** Yes, the glossary is only required when you use a standalone symbol. Not a symbol with adjacent text. The requirement of the glossary is when a standalone symbol is used, that is recognized by an SDO.

That's some of the criteria that was mentioned earlier. It has to meet the criteria to be a standalone symbol.

**(Ed):** The reason I bring this out, is if you look at a lot of medical devices, if you look at the faceplate, if you look at the small screen display, icons that are on there, you know, and I know this is trying to make up for some issues in the past.

There are many, many devices that have nonstandard symbols on them, without accompanying text next to them. And they're out there on the market. So, you know, that's just a fact. And the question is going forward it sounds like you're not going to allow that?

Scott Colburn: Yes, I mean we can't. Yes, to your point what the rule is addressing is the symbols as outlined in there, we, you know, we do know that there are things on the market that may have changed in their final labeling and may not be compliant with that.

And that I think is a risk the manufacturer may take when doing this, such if it determined to be a symbol that is to be used for its labeling then it should try to comply with the relevant parts of the Act.

**(Ed):** Yes. But that's not to say a manufacturer couldn't try to convince the reviewers of their application that they have a situation here, where they can't use a standard symbol. They're using a homegrown one. It works best because of real estate without a text label and they have data.

I realize what I think I'm hearing here is it's not what the FDA wants. But, that doesn't prevent a manufacturer who's trying to make their case.

**Tosia Hazlett:** Yes. In the submission, FDA has the authority to make that definitive determination regarding compliance with the statute, and can take enforcement action against the violation, as warranted.

You also have the option to request recognition of a certain standard, if you don't want to determine that for yourself. You know, or the manufacturer doesn't want to make the determination themselves.

**(Ed):** Thank you.

**Coordinator:** Our next question comes from (Mike). Your line is open.

**(Mike):** Thank you. I want clarification. You talked about the declaration of conformance to standards. Are you indicating that in order to use a symbol, you have to write a declaration that you meet the requirements of that standard, or the sections of that standard for each symbol that you use?

**Scott Colburn:** Yes. So just like in the use of any standard that is recognized by the agency - you would submit a declaration conformity in stating or listing in summary returns that would be enough to identity which symbols you are conforming to in that declaration of conformity.

**Man 2:** Okay, so - okay. Does that declaration just need to be in your 510K and not in any labeling?

**Scott Colburn:** Correct.

**Man 2:** Okay. Thank you.

**Coordinator:** Or next question comes from (Margaret). Your line is open.

**(Margaret):** Hi, I have a question related to - I see previously any questions. We have a product that has international symbols. And those international symbols use the ISO 15223. Currently we're planning to remove the text next to these symbols.

And I like to find out if we have the glossary any IFU, which accompanies each unit will that be adequate for compliance purposes?

**Tosia Hazlett:** Yes

**(Margaret):** Okay, so we don't need to put on the packaging label any references whatsoever? We just need to include the IFU and in the back of the IFU the glossary? Correct?

**Tosia Hazlett:** Yes. So that.if you have a symbols glossary for those symbols you do not need the adjacent text. ..

**(Margaret):** So - I'm sorry go ahead.

**Tosia Hazlett:** Oh no, I was going to say yes. That's fine. Yes.

**(Margaret):** So and also one more question listening to the others is in the glossary it sounds to me that we need to reference the ISO standard and also the reference I.D. of that specific symbol called out in that standard in the glossary. Is that - is that my interpretation correct?

**Tosia Hazlett:** Could you say that again? So yes, in the symbols glossary - it's the actual the SDO established symbol that you're using, the title and the designation number of the SDO developed standard that contains that symbol, the title of the symbol and its reference number.

And then the meaning or explanatory text as - of the symbol as provided in the FDA recognition. Or if that symbol is not in a FDA recognized standard or is not used according to the specifications for the use of that symbol, the explanatory text as it's provided in the standard.

**(Margaret):** I see. So just to summarize that. So in my glossary I should have of course the symbol itself and next to it the text that explaining that symbol. In addition to that is the reference I.D. of that symbol in the recognized standard of 15223?

So in other words the designed reference number of that specific symbol called out in that standard. We're going to provide that in one column. Is that something acceptable?

**Tosia Hazlett:** Yes the - as I understand your question. Yes.

**(Margaret):** Okay. All right, great. That's what I need. Thank you very much.

**Coordinator:** Or next question comes from (Jennifer). Your line is open.

**(Jennifer):** Hi, good afternoon. I have a two-part question. What is the official effective date of the final rule?

**Tosia Hazlett:** September 13, 2016

**(Jennifer):** Okay, so in follow up to that. If we submit 510Ks in this interim period, do we have to submit the labeling that contains the requirements as of now, with the both the symbol and the text? Or can we go with the symbol only labeling for review?

**Tosia Hazlett:** Well the - per the final rule if you - if you want to update the device or the product labeling only by substituting text with one or more standalone symbols that are allowed under the rule, or to remove explanatory text adjacent to such symbols, you do not need to submit a new premarket submission prior to making that change.

**(Jennifer):** Okay, but what if it's a brand new 510K? So like a part that's not on the market yet, we're going to submit the 510K. But the 510K is going to go in prior to September 13th.

Do we - are we allowed to include the symbols only labeling in anticipation of, you know, the effective date of the new rule? Or do we need to supply the labeling that would comply with the requirements by the date that we submit the 510K?

**Scott Colburn:** (Jennifer) just give us one moment here real quick.

**(Jennifer):** Sure

**Scott Colburn:** All right (Jennifer), and thank you for your patience. I just wanted to confirm a few things. So because the rule is in effect in September that's the expectation by the premarket review offices that, that's when they would be following those rules.

Part of that is to allow for appropriate training and discussions to get down into the review levels. So the expectation is for that. That being said I would welcome you to contact the appropriate review office or division to have that discussion to see if they feel it would be appropriate at that time.

**(Jennifer):** Fantastic. Thank you so much.

**Coordinator:** Our next question comes from (Anita). Your line is open.

**(Anita):** Hi, this question has already been discussed. But I'm still not clear on the answer. If the package label for each individual device has the symbol to see the IFU - to reference the IFU, is that enough reference that, that's where the glossary is held? Or does additional statement need to be made?

**Irene Aihie:** No, that's enough.

**(Anita):** I'm sorry what was that?

**Irene Aihie:** Hi. I'm sorry. That is enough. As long as you include the location of the glossary on the label, that's fine.

**Tosia Hazlett:** In the labeling. In the instructions for use.

**(Anita):** Okay, great. So, okay. So we have that symbol and then we don't need to add a statement?

**Scott Colburn:** Correct.

**Tosia Hazlett:** Yes, that's right. And when you say add a statement, the - could you just explain that a little bit more? .

**(Anita):** Yes, so right now we have that - on the device label we have the symbol to reference the IFU but it doesn't say specifically that the glossary is in the IFU. But it does have the symbol to reference the IFU. And that is where the glossary is contained.

**Scott Colburn:** Yes, (Anita), that should be appropriate to use that symbol, you know, consult the instructions for use. And then have - within the instructions for use, which is part of the labeling, that would have the glossary if that's where it's contained. Further clarification: According to the rule, the labeling on or within the package containing the device must bear a prominent and conspicuous statement identifying the location of the symbols glossary.

**(Anita):** Okay, perfect. Thank you very much.

**Coordinator:** Our next question comes from (Dora). Your line is open.

**(Dora):** Yes, my question is really more about of combination products. And as we go through this exercise of assessing our labels, whether or not they need to be up - whether we want to update them and add this - the Standards' Website.

How would we go about submitting these to the agency? I mean have you thought about - do these need to be prior approval supplement, a changes being effective, or can we do this via an annual report? For combination products specifically.

**Tosia Hazlett:** And are you saying that for that combination product that the primary mode of action is that of a device for that combination product?

**(Dora):** No, usually of a drug.

**Tosia Hazlett:** Oh, so the rule applies if the primary mode of action is that of a device, and then standalone symbols could be used for the device constituent part of that combination product. And those are the only two sort of qualifiers involving combination products.

**(Dora):** Okay, so we would have to do that as part of our assessment and then do you have any recommendation on how best to submit that update to the label - labeling, whether it's the IFU or the carton? However we decide to do it.

**Scott Colburn:** If this was a drugly (sic) product and to (Tosia)'s point that you could update your symbols for the areas that are specific to the device constituents part of that, I think you would need to follow device labeling updates per how the submission is outlined in the other center.

If it's CBER or other centers that may have a combination product. Not being familiar with that specifically I don't think I could give you any more definitive information, other than to follow the recommendation of what types of information needs to be supplied at the time of an update in your labeling verses at the next scheduled update.

If it's an annual update or otherwise.

**(Doris):** Okay, Thank you.

**Coordinator:** Our next question comes from (Julie). Your line is open.

**(Julie):** Yes, Hi. Our question is for around the use of nonstandard symbols. I think most of them were answered. We have one follow up question and that is if we are using an electronic IFU can we - with a symbol glossary, can we have a symbol on our package that indicates that we'll be - that the symbol glossary is in the EIFU. Is that acceptable?

**Tosia Hazlett:** And again in the electronic IFU, if it's, a statement, not a symbol in a conspicuous and prominent location so that the glossary can be easily referenced.

**(Julia):** Thank you.

**Coordinator:** Our next question comes from (Cali). Your line is open.

**Scott Colburn:**

**Coordinator:** Your line is open. Your line is open. We're unable to hear you. (Cali), the line is open. Moving on our next question comes from (Shurgda). Your line is open.

**(Shurgda):** Good afternoon, thank you for taking my question. Our device is made of - is the cart, which has multiple components and sometimes the labeling involves multiple labels such as installation, operation and cleaning for one single device.

And individual labels - sorry individual manuals for the part, which goes with the main device. And all of that in included into a cart, like suitcase packaging. And the labeling goes along with it.

So the question is if we chose to use standalone symbols for each of these manuals can we submit a single glossary accompanying with it, or do we have to - put the glossary in each of the IFU manuals for each of the device?

**Tosia Hazlett:** Would the end user be using all of the different parts that you were mentioning?

**(Shurgda):** Right, it's a system, which is supposed to be used together.

**Tosia Hazlett:** I think as long as again, can be easily found, so that if there is a question on any of the parts where a symbol is not known to the individual user and there's question about the meaning about what it is, and it could be found quickly, then I would think that would work or that would be okay.

It's just, you know, we're very specific in saying - making sure that it's in a very conspicuous place so that it could be easily found and there would not be a question as to what the meaning of that symbol is.

**(Shurgda):** Okay, and that make sense. And suppose hypothetically, we chose to go with a conspicuous glossary and we reference that glossary in each of the manuals of different components of that system. Would that be something can be accepted?

**Tosia Hazlett:** Yes.

**(Shurgda):** Okay, that's great. Thank you so much.

**Coordinator:** Our next question comes from (Beth). Your line is open. (Beth Woodhead) your line is open.

**(Beth Woodhead):** Hello. Thank you for taking my question. And I am viewing your slide deck and I'm looking at Slide 9, which talks about the definition of a symbols glossary.

There are a couple of bullet points there that describe what needs to accompany each symbol. So my question is surrounding if I am using ten symbols from 15223, are you saying for each time that symbol is used I must provide, with that symbol, the SDO, the title, designation number and then the reference number for the symbol?

**Scott Colburn:** (Beth), just so I understand your question. So you're asking if, say with in your packaging or parts of the labeling you use the biological risk symbol six different times, does your glossary need to have that listed that many times.

**(Beth Woodhead):** No, let me - let me ask this question ...

**Scott Colburn:** Okay, I just wanted to make sure

**(Beth Woodhead):** No. No. So in the glossary, which will be in the instructions for use. In the glossary if I am using five symbols from the standard 15223. Five different symbols, they're all unique but they're all from that same standard.

**Scott Colburn:** Yes.

**(Beth Woodhead):** Do I have to list the - next to each symbol that standard six different times. Because that's a lot of information.

**Scott Colburn:** Oh do you mean -you mean for each symbol used you have to list it as under 15223- 1 ...

**(Beth Woodhead):** Yes

**Scott Colburn:** … for each symbol.

**(Beth Woodhead):** Yes, and then the rev, and then also the reference for each symbol. Is that what we're supposed to be doing?

**Scott Colburn:** Just give me one moment here. Well I,know, looking at using the example, of 15223, I can't confirm that all but a majority of those symbols contained in there are registered symbols under even ISO 7000, the database.

So, you know, many of them have the registration number. To the point that you have, let's just say they are specific to a particular standard, maybe an E.M. standard that is not registered in ISO for example.

If you have five of them, I think you listed it once but in how you developed your glossary it was clear that these set of symbols came from that standard would be appropriate.

There is some freedom to how the glossary is designed to allow you to do it in the most logical way which should, you know, still be reasonably understood and readable.

But it's designed to just kind of capture for the end user as well as the reviewer to make sure that people understand where that symbol came from. Is it a Registered symbol what's it meaning for use and so forth.

**(Beth Woodhead):** So, let me just. I just want to make sure I understand it. If I have the manufacture symbol, if I have the do not use symbol, if I have the humidity symbol and let's just assume they all come from 15223.

For each one of those symbols do I need to reference ISO 15223, the name of that standard whatever the name of that is symbols used in medical device and then the reference number. Do I need to do it for each of those symbols?

**Scott Colburn:** Again, I think there is a little freedom in how you design your glossary to identify or group certain symbols that came from a bunch of different ones. Now again if they're a symbol that comes out of an ISO standard, my understanding is virtually all of them come underneath ISO 7000.

So you could list them all as under ISO 7000. I mean you have a registration number that's assigned to that. Then you've taken care of Bullet 2 and 3 essentially when you have the title. So there is a little bit of freedom in how you could design it to see what makes most sense.

The key end point and I've said ISO 15223 - has specific symbols but those symbols are also already registered or commonly used symbols that are identified in the ISO 7000 database.

But again a large majority of them those are - those could be identified under ISO 7000 as well. But either would be acceptable.

: Okay, thank you.

**Coordinator:** Our next question comes from (Megan). Your line is open.

**(Megan):** Hi. Thank you for taking my question. I have the same question that was just asked so I'm just going to restate to make sure that I understand correctly. In the glossary where the lists the standards with their adjacent text, we are also going to list the standard number, the recognition number and the title of that standard. Is that correct?

**Scott Colburn:** When you said recognition number are you referring to the recognition number that FDA assigns on recognizing the standard?

**(Megan):** Correct.

**Scott Colburn:** That is not required in the glossary itself. The glossary itself just identifies each symbol, and then the title and designation number of that standard for a grouping of symbols or for each individual one, whatever you determine is most relevant.

And then the reference number is the number that may be assigned to that particular symbol. So if you look into the glossary itself or like 15223-1, each standard is registered under a particular number and that is what we're referring to.

**(Megan):** Thank you.

**Scott Colburn:** You're welcome.

**Coordinator:** Our next question comes from (David). Your line is open.

**(David):** Actually, my question has been previously answered. So you can skip me now.

**Coordinator:** Our next question comes from (Alana). Your line is open.

**(Alana):** Yes, most of my questions have also been previously asked and answered. I guess I just have one more point of clarification. If there is a symbol that is not required by FDA but we do include it on our package labeling, can we also use the same rule?

We can define it in our symbols glossary, which can be physically a part of the IFU.

**Irene Aihie:** Just as long as your use of that symbol doesn't lessen the user's readability of what's required by FDA. You can do that.

**(Alana):** Could you say that a little bit louder? I'm sorry, I could barely hear you.

**Irene Aihie:** Okay, I'm saying for non-required FDA information, if you include in FDA's labeling, as long as it doesn't compromise the required labeling, you can have additional information not required by FDA. Do you know what I'm saying?

**(Alana):** Okay. So this is - yes, I think so. So this is a symbol that was required by TUV to meet, you know, e-regulations. So it's the Do Not Use if Package is Damaged symbol is what was requested.

So I - just based on what you said, I don't see where that would lessen any of the FDA required symbols that are on the labeling. Would you agree with that?

**Irene Aihie:** Correct

**(Alana):** Okay. So we can include the symbol. No text but in the glossary - symbols glossary, define that symbol, state where it comes from in ISO 15223 and define it in there and that should be sufficient.

**Irene Aihie:** Yes

**(Alana):** Okay. Thank you.

**Coordinator:** Our next question comes from (Kim). Your line is open.

**(Kim):** Hi. Yes. I just had a question regarding the RX Only symbol. Is that considered a standalone symbol that would need to be referenced in the glossary?

**Tosia Hazlett:** As you know, previously the RX symbol had a statement that needed to accompany the symbol in a symbol statement so it would be referenced in the glossary. Further clarification: In the new rule, the "Rx Only" is a symbol statement and could be in the glossary, but it is not required to be in the glossary.

**(Kim):** Okay, thank you. And then also, I guess on the previous question, what - on point two of the definition of a symbols glossary slide, what is the designation number? I guess, is that the FDA recognition number or…

**Scott Colburn:** No, it's the number, so, you know, like ISO 7000, right? So 15223-1 those - that number.

**(Kim):** Okay, so we would just need to reference that number and then the title of the standard?

**Scott Colburn:** Correct

**(Kim)** Okay, perfect. Thank you.

**Scott Colburn:** Yes, you would be identifying, let's just say if this is a device that would require premarket submission or if you're utilizing a standard, you would identify the recognition number of that, if you are tying that into a declaration of conformity to identify that it's an appropriate portion. But not as a part of the labeling.

**(Kim):** Okay, perfect. Thank you.

**Coordinator:** Our next question comes from (Luke). Your line is open.

**(Luke):** Yes, hello. Thank you. My question is in the ISO 15223-1 standard, there are certain specific requirements for Europe and we were just wondering to what extent this is also applicable to the U.S.

For example, the manufacturing symbol - this factory symbol is just defined as the manufacturer in the sense of the medical device directive. So do you - do you accept this factory symbol at all or do you overlook this?

Because there could be contradictions between the European manufacturer for the medical device directive and the U.S. sense of the manufacturer, which could be rather a Manufactured For product or Developed For product.

**Irene Aihie:** Are you asking about the country of origin, is that - is that what you're asking?

**(Luke):** No, we are using - just as a designation of the official manufacturer of the product, we use that factory symbol. And my question is just - and right now we are adding the requirements from the FDA that for example, we state that it's not the actual manufacturer.

But it's the specification developer with an added Manufactured For statement for example. So do you recognize this factory symbol at all?

Scott Colburn: If it's a symbol that's contained in the standard then the answer yes, we do recognize those symbols to be placed on, you know, and in this case, while it may not be specifically relevant to the jurisdiction here as far as it's explained appropriately in the guide - in the relevant glossary.

It should be apparent as such but understand that maybe you don't want to have different labels for every jurisdiction. If it's contained in this - in a standard that is recognized or contained in a standard under an appropriate standard developing organization, then the symbol is considered appropriate.

**(Luke):** Okay. And also, there is an additional requirement for certain use symbols in the ISO standard. For example, the Humidity Limitations symbol or this Do Not Use if Package is Broken symbol, that it has to be explained in the information given to the user in Europe specifically.

So is this also applicable to the U.S. or can we use it with that symbol glossary without an additional explanation in the U.S.?

Scott Colburn: So I believe you're referring to the registered symbol under registration number in 2620, which says in Europe, the symbol shall be explained in the information supplied by the manufacturer.

Now that symbol being part of that standard is still appropriate, it's just not being a European expert, my understanding is that Europe does not require by law that the symbols are in a glossary and the instructions for use.

And although many standards do call that out, it is not yet a requirement in Europe. However, there are specific standards where - or symbols that are required to have them explained further in the information supplied.

This would still - if you're following the rules for a glossary and the information contained in the glossary in citing that symbol, you would give the description of that and everything else that's appropriate in the glossary or in the areas for the instructions for use if appropriate.

And that should be satisfactory.

**(Luke):** Okay, good. Thank you.

**Coordinator:** Our next question comes from (Ruth). Your line is open. (Ruth Creed), your line is open. Please check your mute button. Moving on. Our next question comes from (Courtney). Your line is open. (Courtney Nix) your line is open.

**Man 3:** Our question was actually previously answered as well

**Coordinator:** Okay. Thank you. Our next question comes from ((Jody)). Your line is open.

**(Jody):** Hello, did you get my name wrong?

**Coordinator:** I do have you as (Jody). Your line is open and you're currently able to ask your question.

**(Charity):** So my name is (Charity).

**Coordinator:** I apologize.

**(Charity):** But I'm calling - I have two questions. First one is when we talk about reference to ISO 15223-1, are you expecting to see also the year of publication in that? Or are you just expecting to see the name of the standard, or the number of the standard and the title?

**Scott Colburn:** Well I think - to be fair to the information in the bullet - the title designation number should be sufficient. You know, if this is a product that would require a premarket notification or application then in the citing of that standard and the declaration

conformity, you'd have to comply with the requirements of that, which would include the dates and stuff.

But for the purposes of the labeling requirements of the glossary, no that's not required.

**(Charity):** Okay, perfect. Thank you. And then the second one is kind of a little more - I read the preamble and I'm still trying to understand something. So if the symbol itself is clearly defined in the glossary, how is adding the reference value added to the customer? I guess where did that come in?

**Tosia Hazlett:** In some of the determination for this change, there was what was previously in the preamble, there was a need to expand more to make sure that if standalone symbols are being used that the information , the symbol, is in an SDO established standard and some of the other criteria were necessary in order to move forward.

So again, it's an option. It's one option if manufacturers want to use the standalone symbols and if they are used, - you do have to have a glossary.

But if you choose to just keep symbols with adjacent text, that's still allowed as well. So I don't know if I've answered your question or if that's helpful?

**(Charity):** I was just curious because obviously a lot of these standards are large and the titles are long and they're frequently using multiple symbols from the same standard.

So it feels burdensome perhaps that we're applying all of that information in the glossary for all of these products versus just calling out the ones that are non-standard symbols. It's just - I was just curious of the rationale for why the direction went the way it did.

**Tosia Hazlett:** And I think some of the reason is also to just to make sure that the particular symbol would be read, would be understood by the ordinary user, or the device user. So it was to further verify that information, that the symbol was in a recognized standard.

**(Charity):** All right, thank you very much.

**Coordinator:** And our final question for today comes from (Erin). Your line is open. (Erin), your line is open to ask your question.

**(Erin Gulame):** Oh, hello.

**Coordinator:** Yes, your line is open to you to ask your question.

**(Erin Gulame):** We are currently using the guidance for industry use of symbols on labels and in labeling of in vitro diagnostic devices. With this new final rule, are we going to now have to provide a symbols glossary?

**Tosia Hazlett:** Yes.

**Irene Aihie:** That's being withdrawn.

**Tosia Hazlett:** Yes, the guidance is being withdrawn and we certainly appreciate that there's been the industry reliance on the 2004 IVD enforcement discretion policy guidance. And recognize that it addresses some of the requirements put forth in the symbols final rule.

We will be withdrawing the 2004 IVD symbols guidance following the effective date of the symbols final rule. I know there's been a lot of questions about a particular timeframe for that.

So if you believe that FDA should wait after the effective date of the final rule before withdrawing IVD enforcement discretion policy guidance, we'd like to hear that.

**(Erin Gulame):** Okay, thank you.

**Coordinator:** This does conclude the question and answer portion of today's call. I will now turn it back to Irene Aihie, you may begin.

**Irene Aihie:** Thank you. This Irene Aihie, we appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn Webpage, at www.fda.gov/training/cdrhlearn by Tuesday, August 2nd.

If you have additional questions about the final rule, and or notice, please use the contact information provided at the end of the slide presentation. As always, we do appreciate your feedback. Again, thank you for participating, and this concludes today's Webinar.

**Coordinator:** This does conclude today's conference call. We thank you for your participation and you may also disconnect at this time.

END